

Claims

What is claimed is:

- 5        1. A method for modulating an immune response comprising administering a nucleic acid sequence encoding IL-12, IFN- $\gamma$ , or both IL-12 and IFN- $\gamma$ , or biologically active fragments of any of the foregoing; and an operably-linked promoter sequence; to a patient in need thereof.
- 10      2. The method of claim 1, wherein the nucleic acid sequence encodes human IL-12, human IFN- $\gamma$ , or both human IL-12 and human IFN- $\gamma$ .
- 15      3. The method of claim 1, wherein the IL-12 comprises the p35 subunit, the p40 subunit, or both the p35 subunit and the p40 subunit.
- 20      4. The method of claim 3, wherein the p35 subunit comprises the amino acid sequence of SEQ ID NO:8, or a biologically active fragment or homolog thereof, and wherein the p40 subunit comprises the amino acid sequence of SEQ ID NO:10, or a biologically active fragment or homolog thereof.
- 25      5. The method of claim 1, wherein the nucleic acid sequence encodes both IL-12 and IFN- $\gamma$ .
6. The method of claim 1, wherein the IFN- $\gamma$  comprises the amino acid sequence of SEQ ID NO:12, or a biologically active fragment or homolog thereof.
7. The method of claim 1, wherein the nucleic acid sequence encoding IL-12, or both IL-12 and IFN- $\gamma$ , comprises SEQ ID NO:7 or SEQ ID NO:9, or a biologically active fragment or homolog of any of the foregoing.

8. The method of claim 1, wherein the nucleic acid sequence encoding IFN- $\gamma$ , or both IL-12 and IFN- $\gamma$ , comprises SEQ ID NO:11, or a biologically active fragment or homolog thereof.

9. The method of claim 1, wherein the nucleic acid sequence is administered with a  
5 pharmaceutically acceptable carrier.

10. The method of claim 1, wherein the nucleic acid sequence is contained within an  
expression vector.

10 11. The method of claim 10, wherein the expression vector is a DNA plasmid.

12. The method of claim 10, wherein the expression vector is a viral vector.

15 13. The method of claim 1, wherein the nucleic acid sequence is contained within a  
genetically modified cell that expresses the nucleic acid sequence within the patient.

14. The method of claim 1, further comprising administering an antigen to the patient.

20 15. The method of claim 14, wherein the antigen is selected from the group consisting of  
a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant  
nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

16. The method of claim 14, wherein the antigen is administered to the patient as a non-  
antigenic nucleotide sequence encoding an antigenic polypeptide.

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17. The method of claim 14, wherein the antigen is an antigenic nucleotide sequence.

18. The method of claim 14, wherein the antigen is administered to the patient with the  
nucleic acid sequence and a pharmaceutically acceptable carrier.

19. The method of claim 1, wherein the patient is human.
20. A pharmaceutical composition comprising a nucleic acid sequence encoding IL-12, IFN- $\gamma$ , or both IL-12 and IFN- $\gamma$ , or a biologically active fragment of any of the foregoing; an operably-linked promoter sequence; and a pharmaceutically acceptable carrier.  
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21. The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encodes human IL-12, human IFN- $\gamma$ , or both human IL-12 and human IFN- $\gamma$ .  
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22. The pharmaceutical composition of claim 20, wherein said IL-12 comprises the p35 subunit, the p40 subunit, or both the p35 subunit and p40 subunit.
23. The pharmaceutical composition of claim 22, wherein said p35 subunit comprises the amino acid sequence of SEQ ID NO:8, or a biologically active fragment or homolog thereof, and wherein said p40 subunit comprises the amino acid sequence of SEQ ID NO:10, or a biologically active fragment or homolog thereof.  
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24. The pharmaceutical composition of claim 20, wherein said IFN- $\gamma$  comprises the amino acid sequence of SEQ ID NO:12, or a biologically active fragment or homolog thereof.  
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25. The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encoding IL-12, or both IL-12 and IFN- $\gamma$ , comprises SEQ ID NO:7 or SEQ ID NO:9, or a biologically active fragment or homolog of any of the foregoing.  
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26. The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encoding IFN- $\gamma$ , or both IL-12 and IFN- $\gamma$ , comprises SEQ ID NO:11, or a biologically active fragment or homolog thereof.

27. The pharmaceutical composition of claim 20, wherein said composition comprises an expression vector containing said nucleic acid sequence and said operably-linked promoter sequence.

5        28. The pharmaceutical composition of claim 27, wherein said expression vector is a DNA plasmid.

29. The pharmaceutical composition of claim 27, wherein said expression vector is a viral vector.

10      30. The pharmaceutical composition of claim 20, wherein said composition further comprises an antigen.

15      31. The pharmaceutical composition of claim 30, wherein said antigen is selected from the group consisting of a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

20      32. The pharmaceutical composition of claim 30, wherein said antigen is administered to the patient as a non-antigenic nucleotide sequence encoding an antigenic polypeptide.

33. The pharmaceutical composition of 30, wherein said antigen is an antigenic nucleotide sequence.

25      34. The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encodes both IL-12 and IFN- $\gamma$ .

35. An expression vector comprising a nucleic acid sequence encoding both IL-12 and IFN- $\gamma$ , or a biologically active fragment thereof; and an operably-linked promoter sequence.

36. The expression vector of claim 35, wherein said IL-12 comprises the p35 subunit, the p40 subunit, or both the p35 subunit and the p40 subunit.

5       37. The expression vector of claim 35, wherein said expression vector is a DNA plasmid.

38. The expression vector of claim 35, wherein said expression vector is a viral vector.

10     39. The expression vector of claim 35, further comprising a nucleic acid sequence encoding an antigen and an operably-linked promoter.

40. An isolated cell that has been genetically modified with a nucleotide sequence encoding both IL-12 and IFN- $\gamma$ , or a biologically active fragment thereof; and an operably-linked promoter sequence.

15     41. The genetically modified cell of claim 40, wherein said IL-12 comprises the p35 subunit, the p40 subunit, or both the p35 subunit and the p40 subunit.

20     42. The genetically modified cell of claim 40, further comprising a nucleic acid sequence encoding an antigen and an operably-linked promoter.